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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,696	06/27/2005	Katsuro Tachibana	F-8681	9237

28107 7590 03/09/2007
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EXAMINER

LONG, SCOTT

ART UNIT	PAPER NUMBER
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1633

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/535,696	Applicant(s) TACHIBANA ET AL.	
	Examiner Scott D. Long	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/19/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of record has changed. Please direct all further correspondence to Scott Long whose phone number is 571-272-9048.

Election/Restrictions

Examiner acknowledges the election, with traverse, of Group II directed to a delivery apparatus for delivering compounds to teeth or periodontal tissue comprising an ultrasonic transducer and a material ejecting device, in the reply filed on 26 December 2006.

The applicant's traversal is based on 3 points: (1) "it is thought that the two groups of claims are so directly related to each other that it is believed that all of the claims may properly be included in the same application"; (2) there is undue burden for the USPTO to examine divisional applications; and (3) a speech by former Commissioner of Patents given in 1975.

Applicant's traversal has been considered and not found persuasive for the following reasons:

(1) Because the application is a 371 National Stage filing of a PCT, it is subject to PCT Rule 13.1, permitting restriction for inventions not linked by a single general inventive concept. The current examiner agrees with the former examiner, that medical

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materials comprising bubbles, plasmids, and drugs do not share a common inventive concept with an apparatus for delivering agents to a tooth or periodontal tissue.

(2) The laws allowing for restriction have resulted in divisional applications being filed at the USPTO for many years. Frequently, the nature of the subject matter found within divisional applications is distinct enough that the applications are docketed to different art units, to permit examiners with the most appropriate scientific background to examine the applications. Therefore it is not a burden for the USPTO to examine divisional applications, but a necessary service to the applicant, so that he/she may receive the most skilled examination possible.

(3) The examiners are subject to the laws and regulations of the United States of America, regarding patents and to treaties to which the USA is signatory. The speech by Former Commissioner Dann is not law.

Therefore, the restriction is made final.

Claim Status

Claims 1-4 are pending. However, claims 1-2 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 3-4 are under current examination.

Sequence Compliance

Sequence Listing and CRF have been received and are acknowledged by examiner. A statement that the Computer Readable Form (CRF) and the Sequence Listing are identical has been submitted and is acknowledged by examiner.

Oath/Declaration

The oath or declaration, having the signatures of all inventors, received on 27 June 2005 is in compliance with 37 CFR 1.63.

Information Disclosure Statement

The Information Disclosure Statements (IDS) filed on 19 May 2009 consisting of 1 sheet(s) are in compliance with 37 CFR 1.97. Accordingly, examiner has considered the Information Disclosure Statements.

Priority

This application claims benefit as a 371 of PCT/JP03/14953 11/21/2003. This application claims benefit from foreign patent applications (JAPAN) 2002-339944 (filed 11/22/2002) and 2003-389975 (filed 11/19/2003). The instant application has been granted the benefit date, 21 November 2003, from the application PCT/JP03/14953.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Tachibana et al (EP0504881A2, published 23 September 1992).

Claim 3 is directed to an agent delivery apparatus for delivering a therapeutic agent to a tooth or periodontal tissue, comprising an ultrasonic transducer having a tip provided with a detachable ultrasonic emitter for emitting an ultrasonic wave to a target site of a tooth or periodontal tissue, and a medical-material ejecting device for supplying to said target site the medical material. Tachibana et al. teach "a drug administration device used for injecting, pouring, applying or circulating the...pharmaceutical liquid composition" (page 2, lines 42-43). Tachibana et al. also teach, "injecting the...pharmaceutical liquid composition...while applying ultrasound" (page 2, lines 35-36). Tachibana et al. teach, "desired ultrasound is applied by conventional ultrasonic devices which can supply a ultrasonic signal of 20KHz to several MHz" (page 3, lines 30-31). Tachibana et al. teach, "pharmaceutical liquid composition is directly administered to the diseased part with an appropriate device" (page 3, lines 38-39). Tachibana et al. further teach, "the drug administration device comprises...and end tube

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which is to be inserted into the tissue...and through which the pharmaceutical liquid composition is...injected....The end tube is provided with a ultrasonic element (e.g. – a cylindrical ceramic oscillator, etc.)...The ultrasonic element is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit via a conductor” (page 3, lines 40-45). Tachibana et al. also describe “the tip of the end tube” (page 4, line 13).

Claim 4 is directed to The agent delivery apparatus as defined in claim 3, which further comprises a manual control unit including means for adjusting the frequency and intensity of the ultrasonic wave to be generated from said ultrasonic transducer, whereby either one of a plurality of oscillation directions in said ultrasonic emitter can be selected according to changes of said frequency. As cited above, the frequency of the device can be adjusted, “the ultrasonic element is supplied by a ultrasonic signal of 20kHz to several MHz from a ultrasonic oscillation circuit via a conductor” (page 3, lines 44-45).

Accordingly, Tachibana et al. anticipated the instant claims.

Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Rich-Mar (Therasound 3.4 Specifications, 1998, <http://www.web.archive.org/web/19981205143248/http://richmar.web.com/>). and as evidenced by Nakashima et al (Human Gene Therapy. April 2003. 14:591-597)

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Claim 3 is directed to an agent delivery apparatus for delivering a therapeutic agent to a tooth or periodontal tissue, comprising an ultrasonic transducer having a tip provided with a detachable ultrasonic emitter for emitting an ultrasonic wave to a target site of a tooth or periodontal tissue, and a medical-material ejecting device for supplying to said target site the medical material. Rich-Mar sells an apparatus that emits an ultrasonic wave. Nakashima et al. teach the Rich-Mar device for delivering therapeutic genes to teeth (page 592, col.2). The Richmar device allows a choice of detachable probes.

Claim 4 is directed to The agent delivery apparatus as defined in claim 3, which further comprises a manual control unit including means for adjusting the frequency and intensity of the ultrasonic wave to be generated from said ultrasonic transducer, whereby either one of a plurality of oscillation directions in said ultrasonic emitter can be selected according to changes of said frequency. The Rich-Mar device allows manual adjustment of "frequency, intensity" (Richmar, Specification, parag.1)

Accordingly, Rich-Mar as evidenced by Nakashima et al. anticipated the instant claims.

Claims 3-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Ram (US-5,593,304, issued 14 January 1997).

Claim 3 is directed to an agent delivery apparatus for delivering a therapeutic agent to a tooth or periodontal tissue, comprising an ultrasonic transducer having a tip provided with a detachable ultrasonic emitter for emitting an ultrasonic wave to a target site of a tooth or periodontal tissue, and a medical-material ejecting device for supplying

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to said target site the medical material. Ram teaches, a "dental apparatus includes... electrical oscillating drive" (abstract). Ram teaches that the device "includes...a manual frequency selector" (col.2, lines 10-12) which allows the operator to "select any frequency up to 35 KHz" (ultrasonic) range (col.4, line 19). In addition to the ultrasonic waves, Ram teaches "discharge of a flowable material, e.g.,...a therapeutic...agent" (col.2, lines 4-5). Ram teaches that the device comprises "a quickly-attachable coupling...interchangeable heads" (col.3, lines 16 and 19). Ram also describes dental instruments that comprise a "metal tip" (col.1, line13).

Claim 4 is directed to The agent delivery apparatus as defined in claim 3, which further comprises a manual control unit including means for adjusting the frequency and intensity of the ultrasonic wave to be generated from said ultrasonic transducer, whereby either one of a plurality of oscillation directions in said ultrasonic emitter can be selected according to changes of said frequency. Ram teaches, "a manual frequency selector for selecting the frequency of the electrical oscillating drive" (col.2, lines 11-12).

Accordingly, Ram et al. anticipated the instant claims.

Conclusion

No claims are allowed.

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Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long
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Art Unit 1633

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